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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,498	03/16/2001	A. Bruno Frazier	6300.96.1	8953

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EXAMINER

ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,498

Applicant(s)

FRAZIER ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 30-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 30-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02 April 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment/RCE

This is a response to the amendment/RCE dated April 2, 2004. Claims 1-28 and 30-54 are pending.

1. The declaration filed on April 2, 2004 under 37 CFR 1.131 is sufficient to overcome the Allen et al. reference.

Response to Arguments

2. Applicant's arguments with respect to claims 1-28 and 30-54 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 8-11, 13-18, 20-28, 30-32, and 43-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al. in US Patent No. 3,964,482.

Regarding claim 1, Gerstel et al. disclose a microneedle array (10) device having a substrate (such as 14) having a substantially planar major surface and a plurality of hollow non-silicon microneedles (12) on the major surface of the substrate, as recited in columns 4-6 and seen in figure 1-6, with emphasis on column 4, lines 23-35, column 6, lines 30-40 and column 8. Each of the microneedles has a microchannel (11) therethrough that provides communication between at least one input port at a proximal end of each of the microneedles and at least one output port at an opposite distal end that extends beyond an edge of the substrate, as recited in columns 4-6.

Regarding claims 2 and 23, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, microneedles each having a bottom wall, two side walls, and a top

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wall that define a microchannel, necessary of a hollow structure. Given a reasonably broad interpretation, even a tube can be considered having walls.

Regarding claim 3, Gerstel et al. disclose that as applied to claim 2, as well as, a bottom wall is formed at least partially on top of the major surface of the substrate and the side walls and top wall are formed around a removable molding material, as recited in column 8 and column 9.

Regarding claims 4 and 24, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, microneedles that are in a two dimensional array, as seen in figures 1-4.

Regarding claims 5 and 25, Gerstel et al. disclose that as applied to claims 2 and 22, as well as, microneedles that are in a three dimensional array, as seen in figure 2, where the device spans in 3 dimensions.

Regarding claim 8, Gerstel et al. disclose that as applied to claim 1, as well as, microneedles that are aligned substantially parallel to each other on the substrate, as seen in figures 1-4.

Regarding claim 9, Gerstel et al. disclose that as applied to claim 1, as well as, a distal end of each microneedle that extends beyond the edge of the substrate a distance from about 10 μm to about 100 μm , as recited in column 7, lines 60-67.

Regarding claims 10 and 44, Gerstel et al. disclose that as applied to claims 1 and 43, as well as, microneedles having a cross-sectional area in the range from about 25 μm^2 to about 5000 μm^2 , as recited in column 7, lines 52-55. A 15-40 gauge size falls within the range.

Regarding claim 11, Gerstel et al. disclose that as applied to claim 1, as well as, a length of each microneedle that is from about 0.05 μm to about 5 mm, and the width of each microneedle is from about 0.05 μm to about 1 mm, as recited in column 7, lines 40-67.

Regarding claim 13, Gerstel et al. disclose that as applied to claim 1, as well as, a substrate of a material selected from the group consisting of glass, semiconductor materials, metals, ceramics, plastics, and composites or combinations thereof, as recited in column 8, lines 30-60.

Regarding claims 14 and 26, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, microneedles of a material selected from the group consisting of metals, plastics, ceramics, glass, carbon black, and composites or combinations thereof, as recited in column 8, lines 30-60.

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Regarding claims 15, 27 and 45, Gerstel et al. disclose that as applied to claims 1, 22 and 45, as well as, microneedles comprise a metal material selected from the group consisting of nickel, copper, gold, palladium, titanium, chromium, and alloys or combinations thereof, as recited in column 8, lines 30-60.

Regarding claim 16, Gerstel et al. disclose that as applied to claim 1, as well as, microneedles that can withstand flow rates of up to about 1.5 cc/sec.

Regarding claims 17 and 28, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, a coupling channel member (16) that provides fluid communication between the microneedles.

Regarding claim 18, Gerstel et al. disclose that as applied to claim 17, as well as, a coupling channel member is composed of the same material as the microneedles.

Regarding claims 20, 31 and 46, Gerstel et al. disclose that as applied to claims 1, 22 and 43, as well as, microneedles have a plurality of input ports, as seen in figures 1-4.

Regarding claims 21, 32 and 47, Gerstel et al. disclose that as applied to claims 1, 22 and 43, as well as, microneedles that have a plurality of output ports.

Regarding claim 22, Gerstel et al. disclose a microneedle array device (10) having a plurality of hollow non-silicon microneedles (12) having a microchannel (such as 11) therethrough that provides communication between at least one input port at a proximal end of each of the microneedles and at least one output port at an opposite distal end; and at least one structural support member (14) that interconnects the microneedles, as recited in column 4-8 and seen in figures 1-4.

Regarding claims 30 and 49, Gerstel et al. disclose that as applied to claims 22 and 43, as well as, at least one structural support member (14) that precisely controls penetration depth of the microneedles, as seen in figures 1-4. Given the structure, the needles cannot penetrate further than the member (14) permits.

Regarding claim 43, Gerstel et al. disclose a microneedle device (10) having a hollow elongated shaft (12) of a non-silicon material, the shaft defining at least one microchannel (11) therethrough and having a proximal end and a distal end and at least one input port at the proximal end of the shaft and at least one output port at the distal end, the microchannel providing communication between the at least one input port and the at least one output port, as recited in column 4-8 and seen in figures 1-4.

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Regarding claim 48, Gerstel et al. disclose that as applied to claim 43, as well as, a plurality of microchannels (11), as seen in figures 1-4.

Regarding claim 50, Gerstel et al. disclose that as applied to claim 49, as well as, a structural support that is adapted to mechanically fix the microneedle device to the surface that is penetrated by the elongated shaft, given the structure.

5. Claims 51-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Miura et al. in US Patent No. 4,728,392.

Regarding claim 51, Miura et al. disclose a method via providing a substrate (31) with a substantially planar major surface; depositing a metal material (32) on a major surface to form one or more bottom walls for one or more microneedles/nozzles, as recited in column 6, lines 35-65; coating a top surface of the one or more bottom walls with a photoresist layer (33) to a height corresponding to a selected inner height of a microchannel for the one or more microneedles; depositing a metal material to form side walls and a top wall upon the one or more bottom walls and around the photoresist layer; and removing the photoresist layer from the microchannel of the one or microneedles/nozzles, as recited in column 6, lines 35-65.

Regarding claim 52, Miura et al. disclose that as applied to claim 51, as well as, metal material that is deposited by an electroplating process, as recited in column 6, lines 45-47.

Regarding claim 53, Miura et al. disclose that as applied to claim 51, as well as, a metal material that is selected from the group consisting of palladium, titanium, chromium, nickel, gold, copper, and alloys thereof, as recited in column 6, lines 43-50.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 12, 19, 33-42 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al. in US Patent No. 3,964,482.

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Regarding claim 12, Gerstel et al. disclose that as applied to claim 1. However, Gerstel et al. do not explicitly recite a center-to-center spacing between individual microneedles that is from about 50 μm to about 200 μm . On the other hand, it would be obvious to one with ordinary skill in the art to modify the invention to have the needles be spaced as claimed for the purpose of maximizing the amount of needles in a given space.

Regarding claims 19 and 54, Gerstel et al. disclose that as applied to claims 1 and 22. However, Gerstel et al. do not explicitly recite a pair of/plurality of structural support members that mechanically interconnect the microneedles. On the other hand, it would be obvious to one with ordinary skill in the art to modify the invention of Gerstel et al. to include interconnects for the purpose of more precisely controlling penetration depth of the microneedles, as dependent upon the application.

Regarding claim 33, Gerstel et al. disclose a microneedle device (10) having a substrate (14) having a substantially planar surface; and hollow non-silicon microneedles (12) on the planar surface of the substrate, the microneedle having at least one microchannel (11) therethrough that provides communication between at least one input port at a proximal end of the microneedle and at least one output port at an opposite distal end that extends beyond an edge of the substrate. However, Gerstel et al. do not recite only one single microneedle. However, given applicant discloses the embodiments of both multiple and single hollow microneedles, they can be considered equivalents. Thus, it would be obvious to one with ordinary skill in the art to have single or multiple microneedles depending on the application.

Regarding claims 34-37 and 41, Gerstel et al. as modified discloses that as applied to claim 33. See corresponding rejections for claims 9, 10, 13, 15 and 30.

Regarding claims 38-40, Gerstel et al. as modified discloses that as applied to claim 33. Further a microneedle that has a proximal end has a having a plurality of input ports, a plurality of output ports and a plurality of microchannels would further be obvious to one with ordinary skill in the art.

Regarding claim 42, Gerstel et al. as modified discloses that as applied to claim 41, and a structural support that is adapted to mechanically fix the microneedle device to a surface that is penetrated by the microneedle is also within the scope of the invention.

8. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al. in US Patent No. 3,964,482 in view of Ozbay et al. in US Patent No. 5,406,573.

Regarding claim 6, Gerstel et al. disclose that as applied to claim 5. However, Gerstel et al. do not recite a three dimensional array having a plurality of two-dimensional arrays with spacers therebetween. On the other hand, Ozbay et al. teach arrays that are located on a major surface of a substrate, as recited in columns 12-19 and seen in figure 1. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Gerstel et al. to include a three dimensional array having a plurality of two-dimensional arrays with spacers in-between, as taught by Ozbay et al. for the purpose of ease of manufacture and transportation.

Regarding claim 7, Gerstel et al. as modified by Ozbay et al. disclose that as applied to claim 6. Further, it would be obvious to one with ordinary skill for the modification to have the three dimensional array bonded together by a material selected from the group consisting of molding materials, polymeric adhesives, and combinations thereof.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 51-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,876,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because are merely a broader recitation of the same subject matter.

11. Claims 1-28 and 30-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 and 18-24 of U.S. Patent No. 5,871,158. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely a broader recitation of the same subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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